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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/035,408	01/04/2002	David Wallach	WALLACH=17A	3196

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WASHINGTON, DC 20001-5303

EXAMINER
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ANDRES, JANET L

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 08/11/2003

*C*

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/035,408

Applicant(s)

WALLACH ET AL.

Examiner

Janet L. Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 27 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 34-41 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34-37, 40 and 41 is/are rejected.
- 7) ☒ Claim(s) 38 and 39 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 2.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's election of screening methods, species election of NGFR, and amendment to the claims is acknowledged. Claims 34-41 are pending and under examination in this application.

### *Priority*

2. The Examiner notes that Israeli application 112,742, filed 22 February, 1995, contains no reference to RIP or TRADD. These proteins are first discussed on p. 8 and in Figures 2, 3, and 4 of IL 115,289, filed 13 September, 1995, to which the PCT document also claims priority.

### *Claim Rejections - 35 USC § 103*

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
4. Claims 34-37, 40, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tartaglia et al. (Cell, 1993, vol. 74, p. 845-853), Hsu et al. (Cell, 1995,

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vol. 81, pp. 495-504), or Stanger et al. (Cell, 1995, vol. 81, pp. 513-523) in view of Song et al. (J. Biol. Chem. 1994, vol. 269, pp. 22492-22495).

Tartaglia et al. teaches the death domain of TNF-R1 and establishes the corresponding death domain of FAS-R (p. 850, column 2, p. 851, column 1). Tartaglia et al. further teaches that identification of molecules that interact with death domains will be necessary to more fully understand these systems, and teaches that this information might be useful for treatment of disease (p. 851, column 1). Hsu et al. teaches the death domain of TRADD and similarly teaches that it would be useful to identify molecules that bind to it (p. 502, column 2). Stanger et al. teaches the death domain of RIP and also teaches the need for further elucidation of its signaling (p. 520, columns 1 and 2). None of these references teaches the use of the two-hybrid system to identify such molecules. Song et al. teaches such a system and teaches that it useful to identify molecules that interact with TNF-R. It would have been *prima facie* obvious to one of ordinary skill in the art to combine the teachings of Tartaglia et al., Hsu et al., or Stanger et al. to use the two-hybrid system to identify molecules that interact with death domains. One of ordinary skill would have been motivated to do so because each of these references teaches that such identification is useful, and Song et al. teaches a method for such identification.

***Claim Rejections - 35 USC § 112***

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

6. Claims 34-36, 40, and 41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject

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matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

As written, the claims encompass methods of screening for every polypeptides that interact with a death domain, in any and all polypeptides that contain such domains, including those domains and polypeptides not known at the time of filing and those not yet known in the art. Applicant has disclosed five death domain regions. Applicant has not, however, disclosed the death domain sequences of other death-domain containing proteins. No particular characteristics are set forth by which one of skill could identify other members of this genus. Thus one of skill in the art would not conclude that the inventors, at the time the application was filed, had possession of the claimed invention.

7. Claims 34-36, 40, and 41 are also rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods using the known death domains, does not reasonably provide enablement for methods using any and all death domains. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

As stated above, the claimed methods encompass screens using any and all death domains. Because Applicant has not described such domains so that one of skill in the art could recognize and use them in the claimed methods, it would require undue experimentation to practice the invention as broadly claimed.

*Allowable Subject Matter*

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8. Claims 38 and 39 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

CLAIMS 34-37, 40, AND 41 ARE REJECTED. CLAIMS 38 AND 39 ARE OBJECTED TO.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.

Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov](mailto:yvonne.eyler@uspto.gov).

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703)

308-0196.

Janet Andres, Ph.D.

August 8, 2003

  
JANET ANDRES  
PATENT EXAMINER